Remarks

The present amendment cancels claims 1-14, 17, 19-31, 39, 41, 42, 58, 60-62, 64-68, 70-78, 81-86 and 88-96; amends claims 32-38, 40, and 43-46; and adds new claims 96-99. The present amendment is without prejudice to future prosecution.

Applicants request that claim 46 be examined in the present application. Claim 46 is part of Group II (claims 32-57), which was previously elected by the applicants. Claim 46 is a generic claim encompassing the elected species (formula II).

Claim 46 is directed to a peptide, while the prior restriction requirement characterized group II as a mixture of peptides obtained from a library. It respectfully submitted that examination of claim 46 is proper because it was present in the Group II claims and covers the elected species. Peptides present in Group II were not previously restricted. Additionally, claim 45 is directed to a peptide of formula II which now under examination.

Sequence Rule Compliance

Claims 35-38 were objected to for failing to provide sequence identifiers. Claims 35-38 were amended to include sequence identifiers. Such amendments do not narrow the scope of the claims.

Improper Claim Dependency

Claim 33 was objected to for improperly depending from claim 32. The examiner points out that dependent claim 33 is broader than claim 32 and, thus, fails to limit claim 32. Claim 33 was rewritten in an independent claim format as suggested by the examiner.

35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 32-45 stand rejected as allegedly indefinite based on reference to a canceled claim (claim 32); reference to "obtainable" (claims 33, 34 and 45); reference to "figure 7(A)" (claim 35); and reference to G31, F78, R9, D6, M122 and H1 (claims 35-38). The claims were amended to address the concerns raised the examiner. The amendments, which are discussed below, are intended to clarify the claims and not to narrow the claims.

Claim 32 was amended to remove reference to "obtainable from a library according to claim 1" and to indicate comprises an amino acid sequence. Reference to comprises allows for additional amino acids to be present in the peptide. Support for additional amino acids to a referenced peptide is provided by prior reference to "has" as employed in the original claim, and in the specification, for example, on page 20, lines 11-14.

Claim 33 was amended to remove reference to "obtainable" and provide the generic structure of Formula II. Additional amendments were made to further clarify the claim such as replacing "including" with "comprising" and indicating that each of the peptides "comprises" an amino acid sequence provided by Formula II.

Claims 33-35 were amended to provide the sequences for G31, F78, R9, D6, M122 and H1. G31, F78, R9, D6, M122 and H1 are internal designations provided in the specification. The amendment to claim 35 also removes reference to "Figure 7(A)".

35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 39-42 stand rejected as allegedly indefinite based on reference to "peptides in a fusion with additional amino acids" and "at least one other component". Claims 39, 41 and 42, were canceled without prejudice to future prosecution. Claim 40 was amended to more clearly describe a particular fusion.

35 U.S.C. § 112, Second Paragraph (Written Description)

Claims 39-41 stand rejected for allegedly failing to comply with the written description requirements. The patent office argues that reference to fusion with additional amino acids fail to provide a claimed structure or other identifying characteristics for the final composition. The rejection refers to *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) and the patent office written description guidelines.

Claims 39 and 41 were cancelled without prejudice to future prosecution. Claim 41 was amended to more clearly describe the fusion protein.

Applicants note that claims referencing a peptide "comprising" or that "comprises" an amino acid sequence are still pending (see, for example, claims 32-35, 45, and 46). Reference to

"comprising" or "comprises" allows for the presence of additional amino acids and fusion proteins.

Reference to peptides "comprising" or that "comprise" comply with the written description requirement by the peptide structure provided in the claims. The claims provide for a generic structure or specific structure of amino acids that are present. Such a description provides identifying characteristics sufficient to distinguish the peptides from other material.

The court in *University of California v. Eli Lilly* found that support for claims to vertebrate and mammal cDNA provided by general descriptions and a rat insulin nucleic acid sequence were not sufficient to comply with written description requirements. *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In discussing compliance with the written description requirements, the court noted that:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter **sufficient to distinguish it from other materials**. [Emphasis added.]

Id. at 1405, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

In contrast to the situation in *University of California v. Eli Lilly*, the pending claims provide structures distinguishing the claimed subject matter from other materials. The claims provide a generic or specific amino acid sequence. If additional amino acids are present in the peptide, the provided generic or amino acid sequence is also present and is sufficient to distinguish the peptide from other materials.

Further support for the pending claims complying with the written description requirements is provided by Example 13 of the PTO's Synopsis Of Application Of Written Description Guidelines ("Written Description Synopsis"). The Written Description Synopsis is available at http:\\www.uspto.gov/web/patents.guides.htm ("Revised Interim Written Description Guidelines Training Materials").

Example 13 provides an analysis of written description compliance for a claim to an isolated protein "having" a particular sequence described in an application. The analysis describes the claim as a genus directed to proteins comprising a hypothetical SEQ ID NO.

Compliance with the written description requirements was found based on each member of the genus sharing the particular SEQ ID NO as a necessary common feature.

Similarly, the pending claims referencing a peptide "comprising" or that "comprises" a generic or specific amino acid sequence provides a common feature. The description of generic or specific amino sequences provides sufficient written description support for peptides containing additional amino acids.

Accordingly the claims are in condition for allowance. Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, Applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

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Version with Markings to Show Changes Made

Changes to the Claims:

32. (Three Times Amended) A mixture of 108 different peptides, [~~obtainable from a library according to claim 1,~~] wherein each of said 108 different peptides [~~has~~] comprises an amino acid sequence according to the following formula ("Formula II"; SEQ ID NO: 39):

Q	T	H	T	V	G	G	Q	A	S	H	Q	A	S	S	L	T	S	L	F	S	P	G	A	K	Q	N
	T									R							G		L		S					
																	R		Q		P					

33. (Amended Once) A composition [~~including~~] comprising a plurality of peptides, wherein each of said plurality of peptides comprises an amino acid sequence provided by [~~of~~] Formula II (SEQ ID NO: 39):

Q	T	H	T	V	G	G	Q	A	S	H	Q	A	S	S	L	T	S	L	F	S	P	G	A	K	Q	N
	T									R							G		L		S					
																	R		Q		P					

[~~obtainable from a mixture according to claim 32~~].

34. (Amended Once) A composition according to claim 33, wherein said composition consists of [~~including~~] 2 to about 10 different peptides having said amino sequence provided by Formula II (SEQ ID NO: 39) [~~obtainable from said mixture~~].

35. (Amended Twice) A composition according to claim 33, further comprising [~~including at least one of the peptides G31, F78, R9, D6, M122 and H1 of which the amino acid sequences are shown in Figure 7(A)~~] at least one peptide selected from the group consisting of:

G31 TTHTVGGSVARQVHSLTGLFSPGPQQK (SEQ ID NO: 6)

F78 QTHTTGGQAGHQAHSLTGLFSPGAKQN (SEQ ID NO: 19)

R9 QTTVVGGSQSHTVRGLTSLFSPGASQN (SEQ ID NO: 10)

D6 QTTTTGGQVSHATHGLTGLFSLGPQQK (SEQ ID NO: 3)

M122 QTTTTGGSASHAVSSLTGLFSPGSKQN (SEQ ID NO: 23); and

H1 QTHTTGGVVGHATSGLTSLFSPGPSQK (SEQ ID NO: 20).

36. (Amended Once) A composition according to claim 35, wherein said composition comprises [~~including said peptides R9, F78, H1 and D6~~] peptides of SEQ ID NOs: 10, 19, 20, and 3 ("MIX1").

37. (Amended Once) A composition according to claim 35, wherein said composition comprises [~~including said~~] peptides of SEQ ID NOs: 23 and 6 [~~M122 and G31~~] ("MIX2").

38. (Amended Once) A composition according to claim 35, wherein said composition comprises [~~including said~~] peptides of SEQ ID NOs: 6, 19, 10, 3, 23 and 20 [~~G31, F78, R9, D6, M122 and H1~~] ("MIX3").

40. (Amended Once) A composition according to claim 33 [~~39~~] wherein [~~said~~] each of said plurality of peptides consists of said sequence and a hepatitis C virus [~~fusion includes HCV~~] E2/NS1 protein with the peptide in the HVR1 position.

43. (Amended Once) A composition according to claim [~~42~~] 33 wherein said composition [~~includes~~] further comprises a pharmaceutically acceptable excipient.

44. (Amended Once) A composition according to claim [~~42~~] 43 wherein said composition [~~includes an adjuvant~~] further comprises an adjuvant.

45. (Amended Once) A peptide [~~of Formula II obtainable from a mixture according to claim 32~~] comprising an amino sequence provided by Formula II (SEQ ID NO: 39):

Q T H T V G G Q A S H Q A S S L T S L F S P G A K Q N .
T R G L S
R Q P

46. (Amended Twice) A peptide [~~obtainable from a library according to claim 1~~] comprising an amino sequence provided by Formula I (SEQ ID NO: 1):

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Q T H V T G G S A A R  T T S G L T S L F S P G A S Q N
T   T T V     V Q G H A A H S   V G     R L   P K   K
    R         Q V S   Q V R R     R       S   S Q
                                          Q
```